DRAFT PACKAGE INSERT
BAK/Cervical Interbody Fusion System

DEVICE DESCRIPTION

The BAK/Cervical (BAK/C) Interbody Fusion System consists of hollow, perforated, threaded, cylindrical implants. The BAK/C implants are available in four sizes: 6mm, 8mm, 10mm, and 12mm in diameter. All implants are 12 mm in length. Implants are made from titanium alloy (Ti-6Al-4V), conforming to ASTM F136. Instruments designed for implantation of implants are made from stainless steel, conforming to ASTM F899. Implants may be implanted singularly or in pairs at the affected disc level.

INTENDED USE/INDICATIONS

The BAK/C implant is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. BAK/C implants are used to facilitate fusion in the cervical spine and are placed via an anterior approach at the C-3 to C-7 disc levels using autograft bone.

CONTRAINDICATIONS

BAK/C devices should not be implanted in patients with:

- an active infection
- an allergy to titanium or titanium alloy

PRECAUTION

Surgeons should not implant the BAK/C Interbody Fusion System until receiving adequate training regarding the surgical technique. Inadequate training may result in poor patient outcomes and/or increased rates of adverse events. See the BAK/C Interbody Fusion System Surgical Technique Manual for more information on proper implantation technique.

ADVERSE EVENTS

A total of 164 BAK/C device patients and 134 anterior cervical discectomy and fusion (ACDF) patients were enrolled in a multi-center clinical study of the BAK/C Interbody Fusion System. In the BAK/C patient group, the most common adverse event was degeneration of an adjacent disc (6%). Other adverse events that occurred in at least 1% of the BAK/C study population included: continuing or new symptoms (1.9%), degeneration of a non-adjacent disc (1.7%), dural tear (1.3%), incision-related events (1.5%), pseudoarthrosis (1.5%), and vocal paresis (1.2%). See **Table 1** for a summary of adverse event rates observed in the clinical study; events are listed in alphabetical order. The rates in **Table 1** were derived using survival analysis techniques. The product of the proportion of patients free from adverse events over each time interval resulted in the cumulative rates provided in the table.

For the adverse events described in **Table 1**, some patients required additional surgery to treat the complication. The most common of these events was degeneration of an adjacent disc (2.8%). Other adverse events requiring additional surgery in at least 1% of the study population included: degeneration of a non-adjacent disc (1.7%) and pseudoarthrosis (1.5%). See **Table 2** for a summary of the complications that led to surgical interventions subsequent to the clinical trial surgery.

Surgical interventions subsequent to the clinical trial surgery can also by stratified by the types of operations performed. These included *revision, removal, supplemental fixation,* and *reoperation.* See **Table 3** for a summary of the types of additional surgeries that were conducted.

Table 1: Cumulative Complication Rates at 24-Months[1,2]

	BAK/C (%)	Control (%)
Anesthesia-related	0.6	-
Continued/new symptoms	1.9	0.8
Degeneration/adjacent disc[3]	6.0	4.7
Degeneration/non-adj. disc[3]	1.7	-
Dural tear	1.3	-
Dysphagia	0.6	4.5
Implant/Graft collapse	-	6.3[5]
Graft migration	-	0.8
Incision related	1.5	6.9[6]
Increased instability	-	0.8
Myocardial infarction	0.6	-
Pneumonia	0.6	-
Pseudoarthrosis[3]	1.5	4.9
Spinal stenosis	0.6	-
Thrombophlebitis	0.6	-
Vocal paresis	1.2	0.8
Other[4]	2.1	1.5
Total	16.9	25.3[7]

[1] Based on Life Table analysis
[2] Table 4 provides detailed information on the number of patients used to determine these cumulative rates
[3] The likelihood of degeneration of an adjacent disc, degeneration of a non-adjacent disc, and pseudoarthrosis increases over time
[4] Laryngeal spasm, paraspinous spasm, hematoma, nerve root compression, fibrous arthrodesis, injury
[5] Cumulative difference statistically significant at 0.0014 using Wilcoxon (Gehan) statistical test
[6] Cumulative difference statistically significant at 0.0142 using Wilcoxon (Gehan) statistical test
[7] Cumulative difference statistically significant at 0.0178 using Wilcoxon (Gehan) statistical test

Table 2: Complications Requiring Additional Surgery

	Post-op (1 day to 1 ½ Months) Number (%)		3-month (1 ½ months to 4 ½ Months) Number (%)		6-Month (4 ½ months to 9 months) Number (%)		12-Month (9 months to 18 months) Number (%)		24-Month (greater than 18 Months) Number (%)		Cumulative[1] Complication Rate % at 24-months	
	BAK/C n = 154	Control N = 125	BAK/C n = 147	Control N = 118	BAK/C n = 116	Control n = 86	BAK/C n = 126	Control n = 94	BAK/C n = 101	Control n = 80	BAK/C	Control
Continued/new symptoms	-	-	-	-	-	-	1 (0.8)	1 (1.1)	-	-	0.68	0.77
Degeneration adj. disc	-	-	-	-	1 (0.9	1 (1.2)	3 (2.4)[2]	3 (3.2)[3]	-	-	2.79	3.72
Degeneration non-adj. disc	-	-	-	-	-	-	1 (0.8)[2]	1 (1.1)	2 (2.0)	-	1.71	-
Implant/Graft collapse	-	1 (0.8)	-	1 (0.8)	-	1 (1.2)	-	2 (2.1)[3]	-	-	-	3.89[4]
Pseudoarthrosis	-	-	-	-	1 (0.9)	1 (1.2)	1 (0.8)	-	1 (1.0)	2 (2.5)	1.50	2.38
Spinal stenosis	-	-	-	-	1 (0.9)	-	-	-	-	-	0.62	-
Nerve root compression	-	-	1 (0.7)	-	-	-	-	-	-	-	0.62	-
Total	-	1 (0.8)	1 (0.7)	1 (0.8)	3 (2.6)	3 (3.5)	6 (4.8)	7 (7.4)	3 (3.0)	2 (2.5)	6.22	10.78

[1] Based on Life Table Analysis

[2] A single patient experienced 2 separate events (9 months post-operative: adjacent level DDD; 16 months post-operative: disc herniation at a non-adjacent level)

[3] A single patient experienced 2 separate events (10 months post-operative: graft collapse revised with plate and allograft; 13 months post-operative: graft collapse with hardware failure treated with fibular strut, plating and halo application

[4] Cumulative difference statistically significant at 0.0121 using Wilcoxon (Gehan) statistical test

Table 3: Additional Surgery Categories

	Post-op (1 day to 1 ½ Months) Number (%)		3-month (1 ½ months to 4 ½ Months) Number (%)		6-Month (4 ½ months to 9 months) Number (%)		12-Month (9 months to 18 months) Number (%)		24-Month (greater than 18 Months) Number (%)		Cumulative[1] Complication Rate % at 24-months	
	BAK/C n = 154	Control N = 125	BAK/C n = 147	Control N = 118	BAK/C n = 116	Control n = 86	BAK/C n = 126	Control n = 94	BAK/C n = 101	Control n = 80	BAK/C	Control
Revisions[2]	-	-	-	-	-	1 (1.2)	-	-	-	-	0.0	0.99
Removals[3]	-	-	-	-	1 (0.9)	-	-	-	-	-	0.6	1.0
Supplemental Fixation[4]	-	1 (0.8)	-	1 (0.8)	-	1 (1.2)	3 (2.4)[6]	3 (3.2)	1 (1.0)	2 (2.5)	4.3	0.95
Reoperations[5]	-	-	1 (0.7)	-	2 (1.7)	1 (1.2)	2 (1.6)	4 (4.3)	2 (2.0)	-	2.9	0.91
Total	-	1 (0.8)	1 (0.7)	1 (0.8)	3 (2.6)	3 (3.5)	5 (4.0)	7 (7.4)	3 (3.0)	2 (2.5)	6.22	10.78

[1] Based on Life Table Analysis

[2] Revision = An operation that adjusts the implant configuration

[3] Removal = an operation that removes the implant is removed with or without replacing it

[4] Supplemental Fixation = an operation that implants an additional spinal device(s)

[5] Reoperation = an operation that does *not* remove, modify or add any implant components

[6] Total differs from **Table 2** because a single patient had 1 Supplemental Fixation procedure to correct 2 complications (i.e., 1 report of pseudoarthrosis and 1 report of non-adjacent disc degeneration)

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Potential Adverse Effects:

The following is a list of additional adverse effects that may be expected with cervical spinal surgery with the BAK/C Interbody Fusion System, but have not been observed in the clinical study.

- paralysis
- displacement or breakage of the implant
- injury or damage to adjacent bones, discs, or soft tissues (carotid or vertebral artery, nerves, esophagus or trachea)
- death

Note: Additional surgery may be necessary to correct some of these potential adverse events.

CLINICAL STUDY

Study Design & Purpose

The clinical study for the BAK/C Interbody Fusion System compared BAK/C implants to an anterior cervical discectomy and fusion (ACDF) surgical procedure for the treatment of cervical degenerative disc disease. The study was designed as an equivalence trial to evaluate the safety and effectiveness of the device in a prospective, randomized, multi-center, controlled investigation. The effectiveness measures selected for this investigation evaluated whether the affected disc level was fused, whether there was relief from neck pain and radicular symptoms (arm/shoulder pain, loss of muscle strength, sensation abnormalities) and whether there were improvements in patient function (physical and mental). Safety information was measured by an analysis of adverse event reports.

Patients were enrolled in this study according to the following inclusion/exclusion criteria:

Inclusion criteria

- Discogenic radiculopathy of the cervical spine at levels between C-3 and C-7
- Radicular symptoms (arm-shoulder pain, decreased strength, abnormal sensation, and/or abnormal reflexes)
- Discogenic origin of disease confirmed by radiographic analysis, including one or more of the following:
  - ✓ degenerated (darkened) disc on MRI
  - ✓ decreased disc height compared to adjacent normal discs on x-ray, CT or MRI,
  - ✓ disc herniation on CT or MRI

Exclusion criteria:

- Systemic infections
- Significant metabolic bone disease (i.e.,osteoporosis or osteomalacia)
- Circulatory, cardiac or pulmonary problems
- Active malignancy
- Non-discogenic cause of symptoms (e.g., cervical tumor)
- Degenerative disc disease of two or more cervical spine segments
- Previous fusion attempt at same level
- Acute cervical trauma and/or significant instability (i.e., subluxation >3mm on lateral flexion/extension x-rays)
- Rheumatoid disease of the cervical spin
- Moderate to severe myelopathy

Methods

Patients were randomized prior to the implant procedure to the treatment (BAK/C device) or control (ACDF) arm of the study. Autograft and/or allograft were placed into the BAK/C device as part of the implant procedure to facilitate fusion. Patient follow-up examinations were performed post-operatively, and at 3, 6, 12, and 24 months after treatment. Follow-up examinations were also conducted annually after the 24-month time point.

Assessment

Fusion was assessed by review of radiographs. Neck pain status was determined by patient completion of a ten-point visual analog scale. Radicular signs and symptoms measured included arm-shoulder pain, muscle strength, and sensation status. Arm-shoulder pain status was determined by patient completion of a ten-point visual analog scale; muscle strength and sensation status were determined by clinical assessment. Function was assessed by the SF-36 Health Survey. Safety was assessed by completed adverse event reports for reported complications.

Success Criteria

Fusion success was defined as less than 4° of segmental movement on lateral flexion/extension x-rays with less than 2mm of radiolucent lines covering less than 50% of the implant's outer surface as visualized on AP and lateral x-rays. Neck pain success was defined as at least a 2-point improvement in neck pain score in patients with a preoperative score of 4, or maintenance of the preoperative score in patients with preoperative scores of 3 or less. Arm-Shoulder pain success was defined as at least a 2-point improvement in arm-shoulder pain scores in patients with preoperative arm-shoulder pain scores of 4, or maintenance of the preoperative score in patients with preoperative scores of 3 or less. Both limbs must have met the respective success criterion. Muscle strength success was defined as maintenance of or improvement in muscle strength for the deltoids, biceps, and triceps in both arms. Patients presenting with preoperative muscle weakness with pre-op neck and arm-shoulder pain scores of 3 or less must have experienced improvement in the affected muscle group. Sensation success was defined as maintenance of or improvement in sensation response in both arms. Patients presenting with pre-op neck and arm-shoulder pain scores of 3 or less must have experienced an improvement in all preoperative sensory abnormalities. Function success was defined as maintenance of or improvement in the SF-36 score. Overall success was defined as successful outcomes for each of the four previously described study outcomes (fusion, neck pain, radicular signs/symptoms, and function) without the necessity for additional surgery. Effectiveness success was based on a comparison of the overall success rates between the BAK/C and ACDF groups. Safety success was defined as a freedom from all complications rate for BAK/C patients that was equivalent to (i.e., *no worse than*) the complication rate experienced in patients receiving the ACDF procedure.

Statistical Analysis

Safety and efficacy of the BAK/C implants were assessed through Bayesian statistical methods; however, classical statistical analyses were conducted to aid in the interpretation of the study results. The Bayesian approach is a method that can be used to directly address the question of equivalence. Study conclusions regarding both efficacy (outcome measures) and safety (adverse events) were made based on the pre-determined definition of equivalence, specifically, a log-odds advantage of -0.811. Thus, a 90% credible interval that is completely above +0.811 corresponds to a conclusion of superiority; a 90% credible interval that is completely above -0.811 corresponds to a conclusion of equivalence, and a 90% credible interval that contains -0.811 corresponds to a conclusion of no strong evidence for equivalence.

Patient Demographics

Two hundred ninety-eight (298) patients (164-BAK/C patients; 134-ACDF patients) were enrolled at 28 institutions in the United States. Of the patients enrolled, 48.7% were female and 51.3% were male; the mean age at enrollment was 44.1 years. A total of 45.1% patients experienced symptoms of cervical degenerative disc disease with radicular involvement for more than nine months prior to enrollment in the study; 34% had experienced symptoms for between 3 and 9 months and 20.1% had experienced symptoms for less than 3 months. Compensation-related injuries accounted for 29.5% of the study population. The study cohort was comprised of patients employed preoperatively (53.4%), patients unemployed and on disability (32.2%) and patients unemployed for other reasons (14.4%). A total of 40.2% of the study population were smokers preoperatively. There were no statistically significant demographic differences identified between the BAK/C and ACDF patients.

Patient Accounting

As stated previously, patient follow-up examinations were performed post-operatively, and at 3, 6, 12, and 24 months after treatment. Follow-up examinations were also conducted annually after the 24-month time point. Of the 164 BAK/C patients and 134 ACDF patients enrolled, complete safety and effectiveness data were not available for all patients at each follow-up examination. **Table 4** provides a summary of the number of patients who contributed complete safety data at each follow-up interval. Safety data were considered complete if the patient had a completed complication case report form and clinical assessments of fusion and neck pain. The safety analyses were performed on the cohort of all patients enrolled as of June 20, 2000. The denominator for each interval represents the number of patients due for that follow-up evaluation as of June 20, 2000. **Table 5** provides a summary of the number of patients who contributed complete effectiveness data at 6 and 12 months and at 24 months or later. *(Note: The study protocol did not require that complete effectiveness data be collected until the 6-month examination).* Effectiveness data were considered complete if the patient had clinical assessments of fusion, neck pain, radicular symptoms, and function. The effectiveness analyses were performed on the cohort of all patients due for follow-up as of November 17, 1999. The denominator for each interval represents the number of patients due for that follow-up evaluation as of November 17, 1999.

Table 4: Safety Data Accountability

Post-operative		3-month		6-month		12-month		Long-term[1]	
BAK/C x/n (%)	Control x/n (%)	BAK/C x/n (%)	Control x/n (%)	BAK/C x/n (%)	Control x/n (%)	BAK/C x/n (%)	Control x/n (%)	BAK/C x/n (%)	Control x/n (%)
154/164 (93.9)	125/134 (93.3)	147/164 (89.6)	118/134 (88.1)	116/164 (70.7)	86/134 (64.2)	126/161 (78.3)	94/131 (71.8)	101/144 (70.1)	80/118 (67.8)

[1] Follow-up examination conducted at 24 months post-operatively or later

Table 5: Effectiveness Data Accountability

6-month		12-month		Long-term[1]	
BAK/C x/n (%)	Control x/n (%)	BAK/C x/n (%)	Control x/n (%)	BAK/C x/n (%)	Control x/n (%)
114/160 (71.3)	85/130 (65.4)	124/150 (82.7)	94/122 (77.0)	85/101 (84.2)	66/87 (75.9)

[1] Follow-up examination conducted at 24 months post-operatively or later

Results

During the clinical trial, harvesting of additional autograft was not required in the majority of BAK/C implants (51.8%). Only 4.3% of the patients required non-local autograft obtained from the iliac crest. A total of 43.9% of the BAK/C procedures utilized allograft. In the ACDF group, non-local autograft was utilized in 64.2% of the procedures and 35.8% utilized allograft.

The summary information in the following tables provides safety and effectiveness results from the clinical study. **Table 6** provides the study safety results based on the patient population referenced in **Table 4.**

Table 6: Long-Term[1] Safety Results – Bayesian Analysis

Success Measure	BAK/C % Success[2]	Control % Success[2]	Bayesian Analysis Conclusion
Freedom from All Complications	85.1	74.7	Satisfies criterion for equivalence

[1] Follow-up examination conducted at 24 months post-operatively or later
[2] Based on Life Table Analysis of Freedom from All Complications at 24-months

Table 7 provides the study effectiveness results based on the patient population referenced in **Table 5.** Rates of overall study success, fusion, neck pain, radicular, and function success for the BAK/C and ACDF (control) patients are presented.

Table 7: Effectiveness Results - Classical Analysis

	BAK/C % x/n	Control % x/n
Primary Measure		
Overall Success[1]		
6 month	57.9 (66/114)	38.6 (32/83)
12 month	58.9 (73/124)	57.0 (53/93)
Long-Term[2]	65.9 (56/85)	53.0 (35/66)
Secondary Measures		
Fusion		
6 month	99.2 (119/120)	81.9 (77/94)
12 month	97.6 (123/126)	88.7 (86/97)
Long-Term[2]	100.0 (86/86)	95.7 (66/69)
Neck Pain		
6 month	80.0 (108/135)	73.8 (76/103)
12 month	78.3 (108/138)	83.0 (83/100)
Long-Term[2]	84.4 (76/90)	83.1 (59/71)
Radicular		
6 month	61.9 (99/160)	50.8 (66/130)
12 month	75.9 (104/137)	74.0 (74/100)
Long-Term[2]	80.0 (72/90)	76.1 (54/71)
Function		
6 month	81.7 (107/131)	77.9 (74/95)
12 month	74.3 (101/136)	80.0 (80/100)
Long-Term[2]	78.7 (70/89)	75.0 (51/68)

[1] Overall success = successful outcomes for fusion, neck pain, radicular signs/symptoms, and function without additional surgery
[2] Follow-up examination conducted at 24 months post-operatively or later

The Bayesian analysis methods employed to assess safety and effectiveness combine data with a diffuse prior distribution to determine the posterior distribution of the parameters of interest. The posterior distribution of the parameters, in conjunction with certain contrasts of interest, form the basis for determination of success outcomes. The posterior distribution can be summarized by 95% credible intervals. The lower and uppers limits of an interval about a contrast are such that 95% of the posterior distribution is contained between the lower and upper limits of this interval, 2.5% below the lower limit and 2.5% above the upper limit. **Table 8** provides the Bayesian study effectiveness results based on the patient population referenced in **Table 5** by summarizing the lower and upper limits of the posterior distribution of the difference between BAK/C and ACDF success rates for each of the success measures.

Table 8: Long-term[1] Effectiveness Results – Bayesian Analysis

Success Measure		95% Credible Interval for Difference in BAK/C and ACDF Rates (given in %)	Multivariate Longitudinal Bayesian Analysis Conclusion
Primary Measure	Overall Success[2]	(+9.9, +19.0)	Satisfies criterion for equivalence
Secondary Measures	Fusion	(+3.2, +6.1)	BAK/C is superior to ACDF
	Neck Pain	(-5.6, +3.7)	Satisfies criterion for equivalence
	Radicular	(-0.7, +9.3)	Satisfies criterion for equivalence
	Function	(-2.1, +7.1)	Satisfies criterion for equivalence

[1] Follow-up examination conducted at 24 months post-operatively or later

[2] Overall success = successful outcomes for fusion, neck pain, radicular signs/symptoms, and function without additional surgery

CLINICAL RESULTS IN 2-LEVEL PATIENTS

The BAK/C clinical study included patients who received treatment at two contiguous levels. Data were collected from fifty-one 2-level BAK/C patients and twenty-eight 2-level ACDF patients. Results of the statistical analysis performed on 2-level patients were inconclusive and therefore effectiveness and safety for 2-level patients were not established. The BAK/C Interbody Fusion System is not indicated for patients affected with cervical degenerative disc disease at more than one level.

BAK/C IMPLANT STERILIZATION

BAK/C implants are supplied sterile and should be handled in a manner to avoid contamination. In the event of damage to the sterile packaging or inadvertent contamination, implants may be steam sterilized using a gravity cycle of 270°F for 3 minutes. No implant should be re-used if it has come in contact with human tissue or bodily fluid.

BAK/C INSTRUMENT STERILIZATION

Instruments for implantation of the BAK/C device are provided non-sterile and must be sterilized prior to use. *The following instructions apply to instrument cleaning and sterilization*:

1. Rinse the device with warm water for approximately two (2) minutes while brushing with a soft-bristled brush to remove most or all the visible gross debris from the device. Pay careful attention to any pivots, threads, recesses, or crevices on the devices.

2. Ultrasonically clean the device with an enzymatic detergent for five (5) minutes. Scrub the devices using a cleaning brush to remove any visible debris from all crevices.

3. Rinse and flush the device for two (2) minutes with warm tap water.

4. Conduct a final verification of the cleaning process by visually inspecting the device under normal room lighting conditions to verify that all of the foreign material has been removed.

5. Sterilization: Place instruments within Sulzer Spine-Tech sterilization tray. Steam sterilize following AAMI standards and a validated cycle. The manufacturer's recommended cycle is gravity, wrapped, 270° F, for a minimum of ten (10) minutes.

CAUTION: UNITED STATES (FEDERAL) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN WITH APPROPRIATE TRAINING OR EXPERIENCE.

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DRAFT
BAK CERVICAL (BAK/C) INTERBODY FUSION SYSTEM
PATIENT INFORMATION BROCHURE

Introduction
This Patient Information Brochure is provided to help you make an informed decision about your neck surgery, specifically with the BAK Cervical (BAK/C) Interbody Fusion System.

Which Patients Might Benefit from the BAK/C System?
In your cervical spine (neck) there are seven vertebrae (bones). Between each of the vertebra is a disc that is made of a cushion-like material. Motion occurs through the disc. Your disc can become ruptured or collapse, and in some cases excess bone grows along the edges of the vertebrae. As a result of this disc space collapse and excess bone formation, the small spaces that allow nerves to pass through can become narrowed, pinching the nerves and causing neck, shoulder, or arm pain, or numbness. This is often referred to as a degenerative (that is, decreasing in quality) condition of the spine or degenerative disc disease.

Based on your examination, your doctor has asked you to consider a spinal fusion procedure with the BAK/C Interbody Fusion System because of the degenerative condition of the cervical spine. The purpose of this surgery is to stabilize and fuse the disc space between two of your vertebrae in your cervical spine and relieve your neck, shoulder, or arm pain, or numbness. The BAK/C Interbody Fusion System is approved for use in patients with painful degenerative disc disease at one disc level of the cervical spine. The BAK/C device may be placed between the third cervical disc (C-3) down to the seventh cervical disc (C-7).

What is the BAK/C Interbody Fusion System?
The BAK/C Interbody Fusion System consists of implants made from titanium alloy. This material is safe to use with the human body. The implants are similar to hollow screws with holes in them and these devices are implanted singularly or in pairs in the cushion between the vertebrae of the spine known as the disc space. The implants are filled with bone obtained from the front part of the spine during your surgery and/or from your hip.

*****A LINE DRAWING WILL BE ADDED HERE******

When Should the BAK/C Not Be Used?
The BAK/C Interbody Fusion System should not be used in patients with:
- an active infection
- an allergy to titanium metal

What Are Some Possible Complications?
Complications associated with this type of surgery include, but are not limited to, the following:

Complications Associated with the BAK/C Implant
- nerve complications causing pain or physical dysfunction (for example, numbness in arms, hands or fingers; or continuing or increased neck/shoulder/arm pain)
- hoarseness, difficulty swallowing
- dural tear
- spinal fluid leak
- damage to adjacent bones, discs, or soft tissue
- failure to achieve a fusion and new or continued symptoms
- additional surgery (see below)

Additional Surgery*: In a research study conducted by the implant manufacturer, some BAK/C patients needed to have more than one cervical spine operation to resolve ongoing complications. The table below summarizes the percentage of patients that needed more than one operation during the study. The types of operations included:*

Revision: *an operation that adjusts the original implant*
Removal: *an operation that removes the implant and does not replace it*
Supplemental fixation: *an operation that implants additional devices*
Reoperation: *an operation does not remove, modify, or add any implants*

Please talk with your doctor about the results from the research study and the possibility that you might need more than one operation.

Table 1: Complications Requiring Additional Surgery

	Post-op (1 day to 1 ½ Months)		3-month (1 ½ to 4 ½ Months)		6-Month (4 ½ to 9 Months)		12-Month (9 to 18 Months)		24-Month (18 Months or more)		Cumulative Complication Rate Measured at 24-months	
	BAK/C n = 154	Control N = 125	BAK/C n = 147	Control n = 118	BAK/C n = 116	Control n = 86	BAK/C n = 126	Control n = 94	BAK/C n = 101	Control n = 80	BAK/C	Contr
Additional surgery	0	Less than 1%	Less than 1%	Less than 1%	2 ½%	3 ½%	4%	7 ½%	3%	2 ½%	6%	11%

General Surgical Complications
- reactions to anesthesia
- heart attack
- infection
- blood vessel damage/bleeding
- bruise (hematoma)
- pneumonia
- blood clots
- wound closure problems
- death

Please consult your doctor about the complication rates related to treatment with the BAK/C Interbody Fusion System.

What Are Some Benefits of the BAK/C Procedure?
The BAK/C surgery may provide stability to the painful region of the neck by fusing the bone above and below the degenerated disc. When this stabilization is achieved, you may experience relief from neck pain, shoulder pain, arm pain, muscle weakness, and/or numbness. In a research study conducted by the implant manufacturer, 64% of patients who were implanted with the BAK/C device experienced a

successful outcome (fusion of the bone in the spine at the treated level and relief from neck pain, shoulder pain, arm pain, muscle weakness, and numbness). These results are comparable to those experienced in the group of patients receiving an alternative treatment. Please talk with your doctor for a more complete discussion of the results from the research study.

Note: Although this research study included some patients with degenerative disc disease at two disc levels, not enough information was available to determine whether this implant is a good treatment for these patients. This study did not include patients with:

- rheumatoid disease of the cervical spine
- significant loss of quantity or quality of spinal bone (osteoporosis)
- a previous fusion attempt at the same place in the spine

What Should I Do Before Surgery?

It is well known that smokers experience lower surgery success rates than non-smokers. If you smoke, please consider terminating your habit as far in advance of the surgical procedure as possible to increase your chances of a successful outcome. In addition, poor nutrition impacts a body's ability to heal itself. If you eat well-balanced, nutritional meals as far in advance of surgery as possible, this will also help to increase your chances of a successful outcome.

What Happens During the BAK/C Interbody Fusion System Surgery?

Portions of the disc and bone are removed from the front of the spine. The BAK Cervical Implant(s) is advanced into the disc space. One or two devices may be implanted at the affected disc level, depending on your anatomy, surgical exposure, and surgeon preference. Bone graft is placed inside the implant to help bone grow through the implant, bridging the disc space or "fusing" the two vertebrae together.

What Should I Expect After Surgery?

After the surgery is completed, your pain and activity level will continue to be evaluated. You will be expected to see your doctor several times after surgery to evaluate your pain and function. X-rays will be taken to check the BAK Cervical implants. Ask your doctor about the postoperative rehabilitation program and required follow-up. It is important to follow your doctor's directions carefully in order to recover from surgery as quickly as possible.

NOTE: Please call your doctor if you experience any of the following symptoms

- Signs of infection (i.e. fever, chills, redness around incision, increased pain, the feeling of pressure in the neck, or difficulty swallowing)
- Bleeding or excessive drainage from your incision(s)
- Sudden onset of severe pain, or significant increase in your pain level
- Loss of sensation, or significantly decreased sensation in your arms/hands/fingers
- Increased or persistent shortness of breath

Are There Alternative Treatments?
Although your doctor is planning to use the BAK/C Interbody Fusion System for your condition, you should be aware that there are alternative treatments to this type of device. Other treatments may include the following:

- **Surgical**
  Bone grafting techniques have been used to treat degenerative condition of the cervical spine. These procedures are often used in conjunction with surgical removal of the cervical disc with subsequent fusion of the bones. This procedure is known as Anterior Cervical Discectomy and Fusion or ACDF. The fused bones may be reinforced with a metal plate that is attached directly to the affected area of the cervical spine.

- **Non-Surgical**
  Conservative therapies may differ depending on the frequency and intensity of pain. Intermittent pain may be treated with analgesics, muscle relaxants, heat, rest, patient education, stretching exercises, and use of good body mechanics. Continuous pain may be treated with rest, transcutaneous nerve stimulation (TENS), traction, hydrotherapy, strengthening, exercises, local injections, strong analgesics, braces and chiropractic care.

If you want information on these options, please discuss them with your doctor.

Who Do I Talk To if I Still Have Questions?
This brochure is provided to give you information about your treatment options, but it is not intended to replace professional medical care or provide medical advice. If you have any further questions or need additional information about the BAK/C Interbody Fusion System, please call or see your doctor, who is the only one qualified to diagnose and treat your condition.

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